

EXHIBIT B

October 01, 2019

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1
IN THE UNITED STATES FEDERAL COURT
2 FOR THE EASTERN DISTRICT OF PENNSYLVANIA
3

* * *

4 MICHAEL CURRY, : NO. 2:18-CV-00634
5 Plaintiff :
6 :
7 vs. :
8 :
9 CARBOFIX ORTHOPEDICS, :
10 Defendant :
11

* * *

12 Oral deposition of DAVID P. POPE, PH.D.,
13 taken at DUFFY & FULGINITI, 1650 Market Street, 55th
14 Floor, Philadelphia, Pennsylvania, 19103, beginning
15 at 11:10 a.m., on Tuesday, October 1, 2019, before
16 Karen A. Stevens, Court Reporter and Notary Public,
17 there being present:
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25

1 A P P E A R A N C E S :

2

3 KENNETH F. FULGINITI, ESQUIRE
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1 (It is hereby stipulated by and
2 between counsel for the respective
3 parties that signing, sealing, filing and
4 certification are waived; and that all
5 objections, except as to the form of the
6 questions, be reserved until the time of
7 trial.)

* * *

9 DAVID P. POPE, PH.D.,
10 after having been first duly sworn, was
11 examined and testified as follows:

* * *

E X A M I N A T I O N

* * *

15 BY MS. STUPNEVICH:

16 Q Good morning, Dr. Pope. My name is
17 Kateryna Stupnevich. I'm with Morris and Mahoney
18 and I represent the Defendant, Carbofix, in this
19 case. We are going to ask you some questions today.
20 Let me know if at any time you want to take a break.
21 The only caveat is we can't have an open question.
22 So you need to answer the question and then we can
23 break afterwards. Okay?

24 A Okay.

25 Q Have you ever testified as an expert in

1 any litigation before?

2 A Yes.

3 Q How many times approximately?

4 A A hundred.

5 Q When was the last time you testified as an
6 expert in litigation?

7 A That would have been August, I believe.

8 Q Of this year?

9 A Maybe July of this year.

10 Q Have you ever testified as an expert in
11 connection with a litigation concerning orthopedic
12 medical devices?

13 A Yes.

14 Q How many times would you say you testified
15 in those types of matters?

16 A I'm hesitating there because I looked at
17 numerous devices, but how many of them actually were
18 litigated is another question. But I've certainly
19 looked at probably a dozen orthopedic devices of
20 various kinds.

21 Q When you say looked at, you mean opined on
22 various issues that may have been involved but not
23 necessarily pertaining to an ongoing litigation?

24 MR. FULGINITI: Objection to form. You
25 can answer.

1 THE WITNESS: They were all related, I
2 believe, to ongoing or potential litigation,
3 but whether or not I actually ended up
4 testifying, I don't remember.

5 BY MS. STUPNEVICH:

6 Q Okay. Do you recall how many times, if at
7 all, you testified in connection with those types of
8 cases approximately?

9 A It was just a few. I can imagine probably
10 two or three, something like that, but that's a very
11 rough number.

12 Q Sure. When was the last time you
13 testified for such litigation?

14 A That would be probably within the last
15 four years sometime.

16 Q Have you ever testified as an expert in
17 connection with litigation concerning proximal
18 humerus plates or implants?

19 A No.

20 Q What, if anything, did you do to prepare
21 for this deposition?

22 A I simply reviewed the file.

23 Q What are the contents of the file that you
24 refer to?

25 A Certainly the items listed in my report,

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1 which is depositions in my report, the other
2 reports, photographs, Carbofix information, other
3 photographs, reports of the surgery. Probably other
4 things that I can't remember right now.

5 Q Okay. Have you spoken with anyone, other
6 than Mr. Fulginiti or someone from his office, in
7 preparation for the deposition?

8 MR. FULGINITI: You mean not in my
9 presence?

10 MS. STUPNEVICH: Correct.

11 THE WITNESS: With Anthony Bellots.

12 MR. FULGINITI: But that was in my
13 presence.

14 THE WITNESS: Yes, with Mr. Fulginiti.

15 BY MS. STUPNEVICH:

16 Q Outside of Mr. Fulginiti's presence have
17 you spoken with anyone else in preparation for this
18 deposition?

19 A No.

20 Q I have a copy of your Curriculum Vitae
21 here, which is essentially your resume.

22 MS. STUPNEVICH: Let's mark that as
23 Pope-1.

24 * * *

25 (Whereupon, the above-mentioned

1 document was marked for
2 identification as Pope-1.)

3 * * *

4 BY MS. STUPNEVICH:

5 Q Doctor, what is your profession?

6 A I'm a professor of material science at the
7 University of Pennsylvania.

8 Q How long have you held that position?

9 A That position I believe I've held for
10 approximately 45 years.

11 Q How long have you been employed at the
12 University of Pennsylvania?

13 A Fifty-one years.

14 Q What positions have you held at the
15 University of Pennsylvania other than your current
16 position?

17 A Well, I was a junior professor and then an
18 associate professor. So that's the normal thing.
19 And I've had various administrative posts within the
20 university.

21 Q As a junior professor what subject matter
22 did you teach?

23 A I taught things generally in the field of
24 material science; thermodynamics materials,
25 materials properties, things related to material

1 science.

2 Q And as an associate professor what subject
3 matters did you teach?

4 A The same.

5 Q Okay. You mentioned you held various
6 administrative positions there as well. Can you
7 describe some of those for me?

8 A Yes. I've been a department chairman,
9 I've been an associate dean, I've been the ombudsman
10 of the university and I've been chairman of my own
11 department twice and another department once.

12 Q And the department chairman was for which
13 department?

14 A Material science and also for mechanical
15 engineering.

16 Q Throughout your career have you held any
17 positions at any other facilities or institutions?

18 A No.

19 Q Can you please briefly describe your
20 educational background?

21 A Yes. I have a Bachelor's Degree from the
22 University of Wisconsin, a Master's and PhD from
23 California Institute of Technology and also I served
24 as a post-doctoral research fellow at Caltech.

25 Q When did you obtain your PhD?

1 A 1967, as I recall.

2 Q Sorry. You may have said this. From what
3 Institution?

4 A California Institute of Technology.

5 Q You mentioned you were also a
6 post-doctoral research fellow. Where was that work
7 performed?

8 A Also at Caltech.

9 Q How long have you held that position?

10 A How long did I hold it? It was
11 approximately a year and a half, I believe,
12 something like that.

13 Q I'm going to skip around a little bit, but
14 I want to go over some things on your resume.
15 There's obviously a lot. If you can bear with me
16 and follow along, that would be great. Your resume
17 indicates you have published approximately 200
18 publications, I believe; is that correct?

19 A Yes, that's approximately right.

20 Q When was your most recent publication
21 published?

22 A That would have been approximately eight
23 years ago or so, maybe ten.

24 Q Is it fair to say that most of your
25 publications focus on intermetallics, ductility and

1 thermal properties?

2 MR. FULGINITI: Objection to form.

3 THE WITNESS: That's one of the foci, one
4 of the major foci.

5 BY MS. STUPNEVICH:

6 Q What would be some of the other foci that
7 you have?

8 A Things related to behavior of materials at
9 elevated temperature. Maybe that's what you meant
10 by thermal properties.

11 Q Right. Better way to put it.

12 A Things related to what we call phase
13 transformation, things related to the changes that
14 occur inside of the material when you do various
15 things to it, and then things related to the
16 strength and toughness of materials.

17 Q Do you have any publications that focus on
18 orthopedic medical devices?

19 A No.

20 Q Do you have any publications that focus
21 specifically on carbon fibro proximal humeral
22 implants?

23 A No.

24 Q Skipping along to books and chapters,
25 there's plenty of those, too, when was your most

1 recent work published?

2 A You're talking about --

3 Q In books and chapters that you would have
4 contributed to or written.

5 A I honestly don't remember, but it looks
6 like it was the early 2000s.

7 Q Okay. If you had to describe the focus of
8 the books and chapters that you had written for me,
9 how would you describe that?

10 MR. FULGINITI: Objection to form. You
11 can answer.

12 THE WITNESS: The focus of those is rather
13 similar to the focus of my general research;
14 things related to strength, toughness, elevated
15 temperature properties, phase transformations.

16 BY MS. STUPNEVICH:

17 Q And do you have any books or chapters that
18 focus on orthopedic medical devices?

19 A No.

20 Q Any books or chapters that focus on
21 proximal humerus plates?

22 A No.

23 Q Turning to your professional activities,
24 it's over a dozen here with the most recent being
25 1998; is that correct?

1 A Probably right.

2 Q Now, is it fair to say that your
3 professional activities focus primarily on the same
4 things as your publications and the books and
5 chapters you've written?

6 A Yes.

7 Q Did any of your professional activities
8 focus on orthopedic medical devices?

9 A No.

10 Q Did any of them focus on proximal humerus
11 plates?

12 A No.

13 Q There is also a section here about
14 research interests and I think you briefly touched
15 upon that already. Can you elaborate a little bit
16 for me as to the type of research that you have
17 focused on throughout your career?

18 A Yes. Of course the deformation and
19 fracture of the intermetallic compounds,
20 intermetallic compounds are just materials that are
21 comprised of fixed ratios of metals, something like
22 NI3AL. So they have very special properties that I
23 spend a great deal of time studying them. Crystal
24 growth, because when you study those materials you
25 want single crystals so you can study it very

1 carefully, high temperature fracture, because many
2 of these materials are intended for use at high
3 temperatures, so the question is how do they behave
4 at high temperatures. Other questions related to
5 the question of the protection of the metal by some
6 sort of a ceramic overlayer, you know, aluminum
7 oxide or something like that, and that's determined
8 by the strength of the interface between the two.
9 And then finally many materials become brittle at a
10 low or lowish temperature, and that's called the
11 ductile to brittle transition, and that's very
12 important for the behavior of useful materials.

13 Q And so now amongst these research
14 interests, have any of them focused specifically on
15 orthopedic implants?

16 A No.

17 Q And have any of them focused specifically
18 on proximal humerus plates?

19 A No.

20 Q Have you undergone any certifications or
21 training specific to orthopedic medical devices?

22 A No.

23 Q Have you undergone any certifications or
24 training specific to proximal humerus plates?

25 A No.

1 Q Have you studied any materials or
2 literature that's specific to orthopedic medical
3 devices?

4 MR. FULGINITI: Objection to form.

5 THE WITNESS: Certainly the materials
6 themselves related to orthopedic medical
7 devices.

8 BY MS. STUPNEVICH:

9 Q What do you mean by that?

10 A For example, in this matter one of the
11 materials that comes up all the time is the Synthes
12 stainless steel plate, and that is almost certainly
13 a particular grade of stainless steel about which --
14 on which I've done a fair amount of work, for
15 example. Then also this material for the Carbofix
16 plate is made out of a PEEK carbon fiber composite,
17 and that's another interest of mine that I also
18 study. So I'm aware of the properties and I have
19 studied the properties of these composite materials
20 and how the properties of the materials are
21 determined by the various properties of the
22 individual phases.

23 Q Okay. Can you identify some of the
24 literature or materials that you have studied in
25 relation to the PEEK carbon fiber composite.

1 A Well, certainly with regard to this matter
2 I have. There are several papers that were
3 referenced in this matter, and I don't have that at
4 the tip of my tongue, things related to the
5 strength, the bending strength of these composite
6 materials and how they also fail. So those are the
7 main things I have studied.

8 Q How about outside of this matter? Is
9 there any literature that you can specify for me or
10 any materials that you studied pertaining to the
11 PEEK carbon fiber composite?

12 A No, I think I have not, not specific to
13 PEEK carbon fiber. Certainly many polymeric carbon
14 fiber composites, but not necessarily that one.

15 Q Got it. And you referenced for a second
16 there several papers referenced in this matter. Are
17 those things that are referenced in your reports?

18 A I don't recall if it's referenced in there
19 or not. One of them might be.

20 Q And we'll get to the report, so we'll talk
21 about that. Have you studied any material or
22 literature specific to proximal humerus plates
23 outside of this matter?

24 A No -- I should be careful. I mean I have,
25 in your earlier questions about orthopedic devices,

1 of course I've looked at various plates that have
2 failed and those are the stainless steel variety.
3 I'm not certain that they were proximal humerus
4 plates. They were bone plates.

5 Q Okay. But again to clarify, the plates
6 that you have looked at with regard to orthopedic
7 devices and failure have been stainless steel
8 plates. Have you looked at any carbon fiber plates?

9 A I probably have, but I can't quote chapter
10 and verse now.

11 Q Sure. Do you recall when you would have
12 looked at them, how long ago that might have been?

13 A That would have been within the last 10
14 years, because they haven't been around that long.

15 Q Right. Do you recall any specifics about
16 those carbon fiber plates, what type of plates they
17 were or maybe who manufactured them or anything
18 else?

19 A No. I'm having a blank on that. I'm
20 sorry.

21 Q That's okay. Approximately how many
22 carbon fiber plates have you looked at during the
23 last 10 years?

24 A I think it would be one.

25 Q And that's outside of the one involved

1 here?

2 A Right.

3 Q Other than what we have already discussed,
4 can you tell me about any other experience that you
5 have with orthopedic implants?

6 MR. FULGINITI: Objection to form. You
7 can answer if you understand.

8 THE WITNESS: Well, as we talked about
9 earlier, of course the devices and also the
10 devices used for installing them. I have also
11 analyzed various tools and instruments used by
12 orthopedic surgeons.

13 BY MS. STUPNEVICH:

14 Q What kind of devices were those?

15 A Typically rajas. And those are the most
16 common thing.

17 Q Do you have any experience with design of
18 orthopedic implants?

19 A No.

20 Q Do you have any experience with
21 manufacture of orthopedic implants?

22 A No.

23 MR. FULGINITI: You don't mean the design
24 of them. You mean him designing one?

1 BY MS. STUPNEVICH:

2 Q Designing or you participating in the
3 design or being consulted on the design, anything
4 like that.

5 MR. FULGINITI: Again, consulting on the
6 design would implicate everything he's already
7 talked about.

8 MS. STUPNEVICH: Let me clarify.

9 BY MS. STUPNEVICH:

10 Q Have you ever participated in designing an
11 orthopedic implant?

12 A No. The only designing of orthopedic
13 implants I've been involved in have been student
14 projects where they were given the task of trying to
15 design a particular kind of implant. And then of
16 course students love composite materials and so on
17 and so on.

18 Q But you've never had, for instance, a
19 manufacturer or retailer or wholesaler of orthopedic
20 implants involve you in the design process, have
21 you?

22 A I have not.

23 Q And in that same scope, have you ever been
24 involved in the manufacture of orthopedic implants?

25 A No.

1 Q Have you ever performed in or participated
2 in any type of bench testing that pertains to
3 orthopedic implants?

4 MR. FULGINITI: Objection to form.

5 THE WITNESS: The only testing I've been
6 involved in is analysis of implants that have
7 experienced difficulties, problems, broken,
8 that kind of thing, corroded.

9 BY MS. STUPNEVICH:

10 Q Okay. So similarly, is it fair to say
11 that you've never participated in or been involved
12 in any clinical trials pertaining to orthopedic
13 devices?

14 A That's correct.

15 Q And any other studies relating to
16 orthopedic devices other than maybe something that's
17 after the fact when it's already dealing with a
18 fracture?

19 A That's correct.

20 Q Now, other than what we are already
21 discussed, can you tell me about any other
22 experience that you have with proximal humerus
23 plates?

24 MR. FULGINITI: Objection to form. You
25 can answer.

1 THE WITNESS: I think we have covered my
2 experience.

3 BY MS. STUPNEVICH:

4 Q Okay. So again, no participation in or
5 involvement in design of proximal humerus plates?

6 MR. FULGINITI: Same objection.

7 THE WITNESS: Not with manufacturers, as
8 we discussed earlier.

9 BY MS. STUPNEVICH:

10 Q And by extension, no involvement in the
11 actual manufacture of proximal humerus plates,
12 right?

13 A That's correct.

14 Q And also no involvement in any type of
15 bench testing or clinical studies or other trials
16 pertaining to proximal humerus plates?

17 MR. FULGINITI: Same objection.

18 THE WITNESS: Again, related to the
19 manufacture or qualification of these devices.

20 BY MS. STUPNEVICH:

21 Q Sure. Dr. Pope, do you believe you're
22 qualified to ascertain fracture initiation?

23 A Yes.

24 Q Explain.

25 A That's what I do for my life.

1 Q Okay. Do you believe you're qualified to
2 do so specifically with regard to proximal humerus
3 plates?

4 A Certainly with regard to carbon fiber
5 polymeric composite materials, yes.

6 Q Explain to me what makes you qualified in
7 that area, if you don't mind.

8 MR. FULGINITI: Objection to the extent
9 that it calls for a legal conclusion, but you
10 can go ahead and answer.

11 THE WITNESS: Okay to answer?

12 MR. FULGINITI: Yes.

13 THE WITNESS: This composite material,
14 this PEEK carbon fiber composite, is just one
15 example of a polymeric material that is
16 strengthened with fibers. There is a whole
17 universe of such materials, and of course
18 that's a very important universe of materials
19 that people like me are very aware of and study
20 and think about a great deal, and study how
21 the -- what the failure processes are.

22 BY MS. STUPNEVICH:

23 Q And which of your publications or your
24 work deals specifically with PEEK material?

25 MR. FULGINITI: Which of his publications?

1 MS. STUPNEVICH: Either publications or
2 books or chapters that deal specifically with
3 the PEEK material.

4 MR. FULGINITI: Objection to form.

5 THE WITNESS: None of them.

6 BY MS. STUPNEVICH:

7 Q Okay. Dr. Pope, do you hold any
8 professional engineering licenses or certifications?

9 A No.

10 Q Do you believe you can opine on the cause
11 of fracture in this case with any degree of
12 engineering certainty?

13 A Yes.

14 Q Dr. Pope, have you ever met Mr. Curry?

15 A Mr. Curry?

16 Q Yes, the Plaintiff.

17 A No, I have not.

18 Q Have you ever spoken with him?

19 A No.

20 Q Let's get to more of the substantive area
21 of questioning pertaining to what's in your report
22 if that's okay. Did there come a time where you
23 inspected the proximal humerus plate involved in
24 this case?

25 A Yes.

1 Q Do you recall when that inspection took
2 place, ballpark?

3 A No, I don't. But it was on the day that I
4 met you, whenever that was.

5 Q So for the record, it was around March of
6 2019. Do you recall where this inspection took
7 place?

8 A Yes. That was at Micron Laboratories in
9 Wilmington, Delaware.

10 Q Tell me in your own words, if you don't
11 mind, what did the inspection entail?

12 MR. FULGINITI: Objection to form. It's
13 overly broad, but you can answer.

14 THE WITNESS: First the inspection
15 entailed looking at the subject broken plate,
16 photographing it, measuring it in detail,
17 comparing that plate to an undamaged exemplar
18 plate, and then examining the plate in a
19 microscope, looking in detail at the cracks and
20 fracture pattern, and then cutting a sample
21 from the end, the proximal end of the plate,
22 for examination in a cross section in a
23 metallographic sample.

24 BY MS. STUPNEVICH:

25 Q Okay. Did you perform any radiography on

1 the involved plate or exemplar plate?

2 A Yes, we did. We did an X-ray of the
3 subject plate and the exemplar plate.

4 Q What was the purpose of that?

5 A Simply to confirm what we thought was in
6 there, namely the tantalum wire and so on.

7 Q What did you believe the significance of
8 the tantalum wire to be, if anything?

9 A Its purpose, I believe, is simply to be a
10 radio -- an X-ray opaque portion of the plate so it
11 can be seen in radiographs.

12 Q Was there any other objective to
13 performing the radiography?

14 A No, not that I can recall anyway.

15 Q The microscopy that was performed, was
16 that in regard to the involved plate or the exemplar
17 plate or both?

18 A Both, but mostly the involved plate.

19 Q What was the purpose of that?

20 A To study the cracks in the plate, to
21 determine the origin of the cracks and to get an
22 understanding of the numbers and the density of
23 those cracks.

24 Q Other than what we discussed, was there
25 any other testing performed on the involved plate?

1 A I don't think so, but I might think of
2 other things as we go along.

3 Q And now with regard to the exemplar, was
4 there any other testing performed on that?

5 A No, I don't think there was any testing
6 performed on the exemplar other than looking at it
7 and photographing it.

8 Q Was the exemplar looked at under a
9 microscope, if you recall?

10 A Yes, I believe it was.

11 Q Were there any portions of the exemplar
12 that were cut away for testing like what was done
13 with the involved plate?

14 A I believe not.

15 Q You produced a report that documented your
16 findings and conclusions following this inspection,
17 right?

18 A Yes, I did.

19 Q Let's mark that and go through it.

20 MS. STUPNEVICH: Mark this as Pope-2.

21 * * *

22 (Whereupon, the above-mentioned
23 document was marked for
24 identification as Pope-2.)

25 * * *

1 BY MS. STUPNEVICH:

2 Q Dr. Pope, feel free to refer to that as
3 you need. I'll ask you some questions about the
4 findings of your inspection and what's in the
5 report. Did you note any wear patterns in the screw
6 holes of the involved plate during the inspection?

7 A Yes, I did.

8 Q Can you describe those wear patterns for
9 me?

10 A There were two kinds of wear patterns in
11 the screw holes. One is the screw holes through
12 which the fracture passed. That's quite a mouthful.
13 The screw holes that the crack went through. And
14 those screw holes were severely rubbed. They were
15 rubbed smooth. There was rather little detail in
16 the protruding portions of that. The second wear
17 comes from the screws that went into those screw
18 holes, and those threads were deformed by the screw
19 heads.

20 Q If you were to turn to Figure 15 on Page
21 17 of your report, and then also Figure 16 which is
22 on Page 18 of the report, is that what you're
23 referring to here, the two different types of screw
24 hole threading?

25 A Yes, Figure 15 shows threads that were

1 damaged and Figure 16 shows threads that were
2 undamaged because no screw went into that hole.

3 MR. FULGINITI: Just to be clear, that's
4 not all the exhibits that referred to that.

5 MS. STUPNEVICH: Sure.

6 BY MS. STUPNEVICH:

7 Q If you turn to Figure 15, Dr. Pope, what
8 would cause these type of wear patterns?

9 MR. FULGINITI: Objection to form.

10 THE WITNESS: Well, two things. First, in
11 the upper conical portion of the hole, as you
12 can see, there is an area that is a bit rough.
13 And that is almost certainly the result of the
14 screw having been inserted at a slight angle
15 and the head of the screw rubbing against one
16 portion of the hole. The wear patterns in the
17 threads themselves is simply a result of the
18 fact that the hole was pre-threaded, but the
19 threads in the hole don't necessarily match up
20 to the threads that are eventually produced in
21 the bone, and so they have essentially become
22 cross-threaded.

23 BY MS. STUPNEVICH:

24 Q Okay. And with regard to what you had
25 mentioned about the wear pattern where the screw's

1 being inserted and it's being done on an angle and,
2 therefore, damaging that area --

3 MR. FULGINITI: He said slight angle, to
4 be clear.

5 BY MS. STUPNEVICH:

6 Q Aside from the visual inspections, what
7 tests have you done to determine the origin of that
8 wear pattern?

9 MR. FULGINITI: Objection to form.

10 THE WITNESS: Only the visual and
11 microscopic examination.

12 BY MS. STUPNEVICH:

13 Q And what is the basis for your opinion as
14 to that origin?

15 A Simply that the damage follows a helical
16 path that can only be made by a screw thread, and
17 only a screw went into that hole. That was one of
18 the holes through which a screw was inserted.

19 Q Is it conceivable that this damage could
20 have occurred while the screw was being explanted?

21 A No. The screw follows the threads that
22 were produced when it was implanted and, therefore,
23 when it's explanted it would just follow that same
24 path.

25 Q Okay. What type of literature, if any,

1 did you rely on in forming this opinion with regard
2 to the wear pattern?

3 MR. FULGINITI: Objection to form. You
4 can answer.

5 THE WITNESS: I think that I didn't depend
6 on any literature. I relied on my experience
7 about fasteners and threaded fasteners in
8 particular.

9 BY MS. STUPNEVICH:

10 Q So in other words, is it fair to say that
11 based upon just the visual alone you're under the
12 opinion that you can determine the origin of these
13 patterns and what caused them?

14 A Yes, visual and microscopic visual, yes.

15 Q Okay. Were there any other sources that
16 you had consulted in drawing this conclusion
17 pertaining to these wear patterns?

18 A No.

19 Q Now, is it conceivable that these wear
20 patterns could have resulted from just ordinary
21 movement over time of the arm?

22 A No. Such movement would break away the
23 threads. It wouldn't cross-thread the threads.

24 Q You mentioned that the explant of the
25 screw wouldn't create a cross-threading either?

1 A No. It was already cross-threaded during
2 the implant, or I should say implant going in, and,
3 therefore, when going out it would follow that same
4 threaded pattern.

5 Q Is it not possible for a screw to create a
6 cross-thread when it's being removed rather than
7 when it's being inserted?

8 A No. That would be very, very unusual.

9 Q But it's possible?

10 MR. FULGINITI: Objection to form.

11 THE WITNESS: I have never seen it. But I
12 don't think it's possible, but I can't say it's
13 impossible.

14 BY MS. STUPNEVICH:

15 Q Okay. Other than what we have discussed,
16 can you, with a reasonable degree of certainty, rule
17 out any other possibilities for what would have
18 created this wear pattern?

19 MR. FULGINITI: Objection to form.

20 THE WITNESS: I believe that that is --
21 what I just said is true to a very high degree
22 of engineering certainty.

23 BY MS. STUPNEVICH:

24 Q But other possibilities, such as maybe the
25 couple of things I mentioned or maybe a few other

1 causes are something that could have possibly
2 created this as well.

3 MR. FULGINITI: Objection to form. What
4 are you talking about? He's told you the one
5 and only way he knows --

6 MS. STUPNEVICH: If he understands the
7 question, let him answer.

8 THE WITNESS: As I said earlier, I cannot
9 think of another way that you could produce
10 that wear pattern, but I will not definitely
11 rule out any other possibility. But I have
12 never seen one.

13 BY MS. STUPNEVICH:

14 Q Got it. Okay. Do you believe that these
15 wear patterns in the screw holes are indicative of
16 the plate's overall bending strength or do you think
17 that there is a relation between the two?

18 A Yes.

19 Q What do you believe that relation is?

20 A We determined that in these areas where
21 the threads are damaged by the screw threads, that
22 the existing threads are subsequently damaged by the
23 screw. Then we find in those same areas substantial
24 numbers of cracks. And those cracks then grow under
25 the load and greatly reduce the strength of the

1 plate.

2 Q And what testing did you do to arrive at
3 that conclusion?

4 A What?

5 Q What testing did you perform to arrive at
6 that conclusion?

7 A It was the cross sectional examination of
8 the device.

9 Q Can you elaborate on that for me and let
10 me know more about what that entailed?

11 A Yes. To see the cracks in the plate you
12 have to find a way to look inside the plate, which
13 of course is very difficult. So instead, one cuts a
14 cross section through the threaded hole and then you
15 prepare the surface very carefully so it's smooth
16 and scratch-free and so on. And then you look at
17 the threads in cross section across the hole. And
18 then the cracks become easily visible.

19 Q Now, was a cross section cut from the
20 exemplar? I believe you said no earlier, right?

21 MR. FULGINITI: Objection to form.

22 THE WITNESS: From the -- excuse me?

23 BY MS. STUPNEVICH:

24 Q From the exemplar.

25 A No. It was cut from the subject.

1 Q In order to make a determination
2 concerning the cracks and how that relates to the
3 strength of the plates, would there not need to be
4 some sort of comparison involved, that is what the
5 cross section looks like from one subject to what it
6 might look like against another subject?

7 A I don't think that's necessary in this
8 case, because the subject plate had literally dozens
9 and dozens of cracks in it, whereas the exemplar are
10 visible on the surface of the plate, and the
11 exemplar plate had no cracks whatsoever visible in
12 it. And I think it is a reasonable assumption that
13 the exemplar plate was crack free.

14 Q Okay. Now, with regard to this opinion
15 that we were just talking about, did you rely on any
16 literature in support of that or was this based on
17 the testing you've done and your own experience?

18 MR. FULGINITI: Objection to form.

19 THE WITNESS: Two things. One is seeing
20 the cracks themselves and that's a standard
21 metallographic practice. And there is a long
22 literature on that, but it's just a standard
23 procedure. And then the question of what
24 effect do such cracks have on the mechanical
25 performance of a device. And there is a huge

1 literature on that subject as well,
2 particularly in the fatigue literature.

3 BY MS. STUPNEVICH:

4 Q What literature, if any, did you consult
5 in this case with regards to formulating an opinion
6 on what effects the cracks here had?

7 A Yeah. I didn't specifically consult any
8 literature, because I'm familiar with it and have
9 worked with it for years.

10 Q Is there any literature that you can
11 recall off the top of your head that would have been
12 pertinent in this case that you know that applied
13 here?

14 A Oh my. There are books and books written
15 on the effects of preexisting cracks on the fatigue
16 properties of all kinds of different materials. And
17 now you want me to give a specific reference?

18 Q If you can remember.

19 A If I can remember, but of course I can't
20 right now.

21 Q That's okay. Are there any other sources
22 other than what we talked about that you consulted
23 in concluding that there was a connection between
24 the wear patterns in the screw holes and the plate's
25 overall bending strength?

1 A No. I think those were the important
2 features.

3 Q Now, to focus more on those cracks that we
4 had discussed and the substantial wear on the
5 fracture surface, if you can turn to Figure 18 on
6 Page 20 of your report, and you can also take a look
7 at Figure 19 on Page 21. What is identified here
8 with circles and labeled as humerus cracks, is that
9 what you're referring to when you talk about the
10 cracks with substantial wear on the surface of the
11 plate?

12 A These are cracks that resulted from other
13 effects on the plate. The plates -- the cracks that
14 I'm referring to are the cracks that are very close
15 to the threaded holes and are down inside the plate.

16 Q Is there a better -- looking through these
17 figures and images, is there a better picture that
18 identifies the cracks that you're referring to?

19 MR. FULGINITI: Do you mind if I step out
20 for a second while you're doing that?

21 * * *

22 (Whereupon, a brief recess was taken.)

23 * * *

24 THE WITNESS: In answer to your question,
25 Figures 34 through 41 on Pages 35 through 42 of

1 my report.

2 BY MS. STUPNEVICH:

3 Q Okay. And within those figures can you
4 point out to me exactly what you mean when you talk
5 about substantial cracks or where in the image
6 you're referring to?

7 A Yes. Probably the best place to start is
8 on Page 38 in Figure 37. I think the cracks there
9 are quite obvious. And then they're enlarged and
10 you can see the smaller cracks in Figure 38 on Page
11 39.

12 Q Okay. And so the figures that you're
13 pointing to, these are the microscopic images of
14 essentially 35, am I correct, that area where the
15 plate had separated?

16 A Yes. These are the microscopic images of
17 Figure 35 -- yes. Yes, they're the little red
18 dotted squares that show where those photographs
19 were taken in Figure 35.

20 Q What is unusual about these cracks to you
21 that would signify that has some sort of effect on
22 the overall bending strength?

23 MR. FULGINITI: Objection to form. You
24 can answer.

25 THE WITNESS: There is nothing unusual

1 about these cracks. They behave like any other
2 crack does, and that is that when a load is
3 applied to a material that contains a crack,
4 that the stresses, the tendency for the
5 material to break at the very tip of the crack,
6 is hugely magnified and the crack wants to grow
7 and they do grow. And then once the crack is
8 there they will grow relatively rapidly,
9 whereas if there is no preexisting crack, then
10 you have to form a crack, and that's much more
11 difficult. So a crack grows easily, but it
12 nucleates, it forms, with difficulty.

13 BY MS. STUPNEVICH:

14 Q And your testimony is that these were
15 preexisting cracks?

16 MR. FULGINITI: Preexisting? Objection to
17 form.

18 THE WITNESS: These were cracks that were
19 existing once the screw was inserted in the
20 hole.

21 BY MS. STUPNEVICH:

22 Q And how do you know that? What is your
23 basis for that opinion?

24 A Because the hole is so badly deformed and
25 damaged and you can see that the cracks come from

1 those damaged areas of the hole.

2 Q Can we look at Figure 18 for a second?

3 A Figure 18.

4 Q Yes, on Page 20.

5 A Okay.

6 Q Did you examine or inspect the large holes
7 that are on the left side and on the right side of
8 the plate?

9 A I believe I did. And as I recall,
10 those -- yes, I looked at all the holes and those
11 holes, as I recall, did not have screws in them.

12 Q Okay. Did you find those holes to have
13 any type of damaged threading at all?

14 A No, I did not.

15 Q Can you take a look at Figure 17, which is
16 on Page 19.

17 A (Witness complies.)

18 Q Having inspected this part, can you
19 identify for me which of the holes had screws in
20 them?

21 A Yes, I can. Give me a moment.

22 Q Take your time.

23 A So referring to Figure 17, which is the
24 same surface as is viewed in Figure 8, and so in
25 figure 8 if we look at the exemplar plate, then

1 there are screws in holes number 1, 2, 3, 4 and 5.

2 Q Okay. And now if we were to utilize the
3 same numeration for the involved plate, did you
4 inspect all of those screw holes?

5 A Oh, yes.

6 Q And which screw holes did you find damaged
7 worn threads in?

8 A In the holes in which screws had been
9 inserted.

10 Q Was that in each of the holes in which
11 screws had been inserted?

12 A Yes. There were varying levels of damage,
13 but, yes, in all of them.

14 Q If we are looking at the exemplar plate,
15 it looks like there were screws inserted in 1, 2, 3,
16 4 and in addition to 5, right?

17 A Yes.

18 Q So then on the involved plate you have
19 found damage in 1, 2, 3, 4 and 5?

20 A Yes. But we did cross sectional
21 examination, that is to say we did the destructive
22 examination of hole number 1, as I recall, but let
23 me double check that. No, it was hole number 2 was
24 sectioned.

25 Q You had testified earlier that the cross

1 sectional testing that you performed is what led you
2 to conclude that the wear patterns were connected to
3 the strength of the plate; is that right?

4 MR. FULGINITI: Objection to form.

5 THE WITNESS: The wear patterns were
6 connected to the cracks in the plate, and the
7 cracks in the plate are related to the strength
8 of the plate.

9 BY MS. STUPNEVICH:

10 Q Okay. Now, seeing as how the cross
11 section was taken from a place other than the site
12 of the fracture, can you explain to me how you've
13 arrived at that conclusion?

14 A The conclusion being that the site of the
15 fracture was also compromised by the same mechanism?

16 Q Right. I guess my question is, if you're
17 taking a cross section from a different location,
18 what is the basis for drawing that conclusion as to
19 another location?

20 A Well, of course we looked very carefully
21 at the screw threads in the subject plate in hole
22 number 5, which is the one where the crack passed
23 through, and we find that A, the surface looks
24 exactly the same as in the other cases, and B, we
25 found that there were cracks coming out of the

1 damaged hole as well. And so we see the same thing
2 that we saw in the other holes.

3 Q But the other holes did not experience
4 fracture?

5 A They did not. That's correct.

6 Q If we can go back to Figure 17 on Page 19,
7 you've identified in your report numerous cracks
8 which appear to be on the surface of the plate, not
9 inside of the screw holes. That's what's circled
10 here?

11 MR. FULGINITI: Objection to form.

12 THE WITNESS: That's right. They're on
13 the surface, but they extend into the screw
14 holes, yes.

15 BY MS. STUPNEVICH:

16 Q What's the significance of this, in your
17 opinion?

18 A These cracks are not the result of
19 inserting screws in the screw holes. I'll put it a
20 different way. These cracks were not formed by the
21 threads when the screws were put into the screw
22 holes. These cracks were formed by twisting of the
23 plate when it was screwed down in place on the bone.

24 Q How do you know that?

25 A Because that's the only way that such a

1 stress could be applied to this plate.

2 Q Is it conceivable that these cracks were
3 formed just as a result of ordinary movement once
4 the plate was attached to the bone?

5 MR. FULGINITI: Objection to form.

6 THE WITNESS: I seriously, seriously doubt
7 that.

8 BY MS. STUPNEVICH:

9 Q Is it conceivable that these cracks were
10 maybe formed during the explant of the plate?

11 A No.

12 MR. FULGINITI: Objection to form.

13 THE WITNESS: Definitely not.

14 BY MS. STUPNEVICH:

15 Q And why do you say that?

16 A During the explant the screws are just
17 taken out and the surgeon reaches in with forceps
18 and lifts it out of there. There's photographs
19 showing him doing that.

20 Q What about these cracks makes you conclude
21 that they only could have been formulated during the
22 implant when force was utilized to screw in the
23 plate?

24 A The plate is designed to take bending
25 stresses, that is to say to be bent along its

1 length, and, therefore, the stresses that result
2 from that bending point in the direction along the
3 length as well. These cracks were formed by
4 stresses that point 45 degrees away. They're
5 lateral stresses that formed that. And the bending
6 stresses would not, A, produce that kind of a
7 direction and, B, the bending stresses are zero at
8 the end of the plate, whereas the cracks run all the
9 way to the end of the plate.

10 Q So if I understand correctly, is it really
11 the direction of the cracks that's leading the basis
12 for your opinion? In other words, had the cracks
13 been going in a different direction would that
14 change your conclusion?

15 MR. FULGINITI: Objection to form.

16 THE WITNESS: It's the direction of the
17 cracks and the position of the cracks.

18 BY MS. STUPNEVICH:

19 Q Position meaning their location relative
20 to the screw holes?

21 A No. Relative to the end of the plate, for
22 example, in Figure 19.

23 Q Elaborate on that for me. What is the
24 significance of them being towards the end of the
25 plate?

1 A Well, as that figure points out, the major
2 stresses applied to this plate are these bending
3 stresses we are talking about, the stresses that the
4 manufacturer applies when they do the fatigue
5 testing and so forth, the fatigue and strength
6 testing on the plate. But those stresses must be,
7 absolutely must be zero, at the end of the plate.
8 There is no stress at the -- bending stress at the
9 end of the plate. And, therefore, if cracks exist
10 at the end of the plate they can only be the result
11 of some stresses from another source.

12 Q Okay. Is there -- can these cracks be
13 explained by any other cause except possible
14 exertion of force during implantation?

15 MR. FULGINITI: Objection to form.

16 THE WITNESS: That's the only one that
17 makes physical sense.

18 BY MS. STUPNEVICH:

19 Q Okay. You also note in your report severe
20 delamination between layers of carbon fibers
21 resulting from large cracks. Do you mind going
22 through some of these figures for me and pointing me
23 to what you're referring to when you say that?

24 A Yes.

25 MR. FULGINITI: Yes, you mind?

1 THE WITNESS: Sorry. Well, referring to
2 Figure 19, since we are there, all of those
3 cracks show delamination between the matrix and
4 the carbon fibers, because the carbon fibers
5 run parallel to those cracks. So a fiber
6 reinforced material like this product is very
7 strong parallel to the fibers. It's like wood.
8 Wood is very strong parallel to the grain.
9 This material is very strong parallel to the
10 fibers. But perpendicular to the fibers, like
11 perpendicular to the grain with wood, it's much
12 weaker.

13 BY MS. STUPNEVICH:

14 Q And how did you determine the fiber
15 direction?

16 A Because you can see that.

17 Q Point me to it. Explain to me what you
18 mean.

19 A You need to look at higher magnification
20 to do that.

21 Q Do we have any figures that would show us
22 the magnification?

23 A I think not, no.

24 Q What makes you say that the delamination
25 was caused by cracking?

1 A I'm sorry, what makes me?

2 MR. FULGINITI: Objection.

3 BY MS. STUPNEVICH:

4 Q What makes you say that the delamination
5 between the layers of the carbon fiber was caused by
6 cracking necessarily?

7 MR. FULGINITI: Objection to form.

8 THE WITNESS: Well, there's only two
9 choices, right? Either the layers were never
10 properly joined together in the first place,
11 which I think is not credible, or B, they
12 cracked apart at some later time. And
13 delamination is the easiest form of cracking in
14 a material like this.

15 BY MS. STUPNEVICH:

16 Q What other forms of cracking are there in
17 materials like this?

18 A You could have cracking perpendicular to
19 the fibers, and there are examples of that as well.
20 Those are particularly damaging.

21 Q What is that significant of?

22 A Because they -- those cracks are driven by
23 the maximum stress, maximum bending stress. So once
24 they get started, they can do a great deal of
25 damage.

1 Q Wear on the plates are those perpendicular
2 cracks that you're referring to?

3 MR. FULGINITI: You're asking him to find
4 an exhibit?

5 BY MS. STUPNEVICH:

6 Q If you can, yes.

7 A Well, for example, in Figure 15 on Page
8 17, in the area where we were talking about the
9 damage to the top of the screw hole, there is a
10 white line that extends more or less straight up on
11 the top of the plate, and that's one such crack.

12 Q So the cracks that are perpendicular are
13 the ones where the plate is undergoing the most
14 stress?

15 A That's right.

16 Q Did you see any such cracks in hole
17 number -- what I'm going to refer to as hole number
18 5 in the plate based upon the numeration on the
19 exemplar from Figure 8?

20 MR. FULGINITI: Objection to form.

21 THE WITNESS: There are quite a lot of
22 them, but there is only one that I can point to
23 that is visible in these figures. But they
24 would be visible in other figures that are part
25 of the data file. But if you refer to Figure

1 10, there are cracks that -- there is a crack
2 visible that emanates out of the lower partial
3 hole there. And that is one such crack.

4 BY MS. STUPNEVICH:

5 Q If these perpendicular cracks are
6 indicative of the areas where the plate has
7 undergone maximum stress, wouldn't it follow that a
8 fracture would likely occur in that area?

9 MR. FULGINITI: Objection to form.

10 THE WITNESS: Yes. And it did, yes.

11 BY MS. STUPNEVICH:

12 Q But yet we were looking at, for instance,
13 Figure number 15, where we have that type of
14 perpendicular crack within the screw hole, but this
15 is not where the fracture site was.

16 MR. FULGINITI: Objection to form.

17 THE WITNESS: I see what you mean. There
18 are two factors that determine how rapidly the
19 crack grows. One is if you have a preexisting
20 crack it really wants to grow. That's the
21 first thing. But the stress in the device is
22 not uniform and the stress is most highly
23 concentrated in the area where it actually
24 fractured. So the short crack that I showed
25 you, in Figure 15 I think it was, is in an area

1 where the stress is substantially lower than it
2 was in the area shown in Figure 10.

3 BY MS. STUPNEVICH:

4 Q With regards to the delamination between
5 the layer of carbon fiber, can you go over the type
6 of testing that you did to determine the origin of
7 that delamination?

8 MR. FULGINITI: Objection to form.

9 THE WITNESS: Well, again, referring to
10 Figures 37 and 38 on Pages 38 and 39 of the
11 report, for any kind of a fracture and cracking
12 analysis, the purpose of analysis is to see the
13 cracks. If something is broken it's possible
14 that it's broken but there are no short cracks
15 remaining in the material. That means one
16 large crack went through or it broke by some
17 other mechanism. In this case the area
18 surrounding this hole that was sectioned is
19 just riddled with cracks. And these cracks, if
20 they have an appropriate stress about them,
21 will propagate very quickly.

22 BY MS. STUPNEVICH:

23 Q So to go back to my question, as far as
24 the tests that were done to determine the origin of
25 this, was it just the microscopic imaging?

1 A Yes.

2 Q And was there any literature that was
3 consulted in formulating your opinions on this
4 issue?

5 A Well, again, I'm referring to the vast
6 literature that exists in material science about the
7 effects of cracks on particularly the fatigued
8 properties of the materials. So that's the crux of
9 the entire field, is to find the cracks, to follow
10 their progression, and see how fast they move.

11 Q But you didn't consult anything specific,
12 any specific materials?

13 A No. I'm so familiar with it.

14 Q Okay. Is it conceivable that maybe there
15 is another explanation for the delamination? For
16 instance, could it be that the carbon fiber layering
17 that you talked about is something that's common to
18 the PEEK carbon fiber composite material?

19 MR. FULGINITI: Objection to form.

20 THE WITNESS: I don't understand the
21 question. Are you saying that possibly when
22 the carbon fiber reinforced composite is
23 manufactured, that it is manufactured with
24 preexisting cracks?

1 BY MS. STUPNEVICH:

2 Q No. Let me rephrase my question. The
3 delamination that you're referring to, is that
4 something that may be specific to carbon fiber PEEK
5 material in general, as opposed to say titanium or
6 stainless steel?

7 MR. FULGINITI: Objection to form.

8 THE WITNESS: As opposed to what?

9 BY MS. STUPNEVICH:

10 Q Titanium or stainless steel.

11 A Oh, yes. Yes, absolutely. This
12 delamination depends on the anisotropy of the
13 material. Ordinary pieces of wood split, right?
14 That's delamination between the cellulose fibers and
15 the lignin in the wood. But something like titanium
16 or stainless steel is not isotropic in that same way
17 and, therefore, cracks do not form between foreign
18 bodies, because they are all the same bodies within
19 the material.

20 Q Is there anything individual about the
21 PEEK material that can make the cracks present in
22 this type of way?

23 A No. The only thing about the PEEK
24 material is its anisotropy both in terms of its
25 structure and its strength. So the strength is

1 maximum along the length of the fibers and it is
2 minimal perpendicular to the fibers. So the cracks
3 will always try to grow parallel to the fibers. And
4 that's the delamination you're talking about.

5 Q Now, your report also indicates that the
6 stripped screw hole is subjective of the fact that a
7 very substantial force was used -- or rather was
8 required to properly seek the placement bone.

9 MR. FULGINITI: Sorry, what page again?

10 Is it the bottom of Page 3 going on to 4?

11 MS. STUPNEVICH: Here we go. Page 4.

12 Paragraph that starts with "Microcracks."

13 BY MS. STUPNEVICH:

14 Q And on line 3, "Furthermore, the badly
15 damaged and stripped screw hole indicates that a
16 very substantial force was required to properly seat
17 the plate on the bone."

18 A Yes.

19 Q Can you quantify for me the type of force
20 or torque that you think would be required to
21 properly seat the plate on the bone in this case?

22 A I know that the torque and the resulting
23 force was not enough to embed the head of the screw
24 into the plate. And so it wasn't excessive in the
25 sense that the plate -- that it was over-torqued.

1 On the other hand, it was -- the torque was enough
2 such that the screw, when it was inserted in the
3 hole, was cross-threaded in the hole. And as we
4 know, if you cross-thread screws in holes, it takes
5 more torque to put them in.

6 Q So is your position that the surgeon that
7 implanted the plate did not utilize excessive force
8 in -- during the implantation?

9 A I see no evidence of excessive force,
10 because I think if there were excessive force the
11 screw head would have been embedded in the plate in
12 the same way that if one uses excessive force in
13 screwing a -- putting in a screw into a piece of
14 wood. The screw head will also embed into the wood.
15 And I see no evidence of that.

16 Q Okay. As part of your preparation of this
17 report, did you review the operative reports that
18 were authored by the surgeon who performed
19 Mr. Curry's implant surgery?

20 A I certainly reviewed his deposition and I
21 reviewed parts of the operative reports, yes.

22 Q Okay. Is there anything in the report
23 that suggests that either his technique was improper
24 or that he had difficulty with trying to align the
25 plate to the bone?

1 A I see no evidence of that. I think the
2 terms were used that things were routine or
3 whatever. There was no evidence that there was any
4 difficulty.

5 Q So then explain to me what you mean when
6 you say that the stripped screw indicates that a
7 very substantial force was required to properly seat
8 the plate on the bone.

9 A Well, like I said, when the threads are
10 cross-threaded like that it takes more torque. But
11 also in order to crack the plate in the way we see
12 it, it requires a bending in the direction
13 perpendicular to the length of the plate. And
14 therefore it was sitting initially not flat on the
15 bone and the side was pulled down to make contact.

16 Q But your position is that in order to pull
17 it down a substantial or excessive force is not
18 required?

19 A Certainly more than if it were not
20 cross-threaded, if it were not pulled down. But it
21 appears to me that the screw did not bury its head
22 in the material and, therefore, it wasn't excessive
23 in terms of what the material could tolerate.

24 Q Now, if the plate had fractured during the
25 implantation, even if it was a partial fracture, is

1 this something that would have been immediately
2 noticeable?

3 A Not necessarily, no. That's one of the
4 problems with small cracks, is that the most
5 dangerous cracks are the ones that exist that you
6 don't know are there. So, no, you wouldn't
7 necessarily see those.

8 Q Would it have necessarily made a sound if
9 it wasn't visible?

10 A Not necessarily, no. Because this
11 material is not like glass, where it would go ping
12 or something like that. It's a much more ductile
13 material.

14 Q But it's possible that it would have made
15 a noise or a crack would have appeared immediately?

16 MR. FULGINITI: Objection to form.

17 THE WITNESS: I believe there were cracks.
18 Whether they would have appeared immediately,
19 whether they would have been visible to the
20 people watching this procedure is quite another
21 matter.

22 BY MS. STUPNEVICH:

23 Q Now, later on in your report you also
24 indicate that the PEEK carbon fiber composite
25 material is uniquely susceptible to cracking.

1 What's your basis for that opinion?

2 A This is the same thing that I was saying
3 earlier. That one puts carbon fibers -- one puts
4 fibers like for example fiberglass into a material
5 to increase its strength in one direction. That's
6 normally what is done. So you get a very good
7 strength in one direction, but you pay for that with
8 a very reduced strength in the perpendicular
9 direction. That's why it's called anisotropic. So
10 first of all, it has this great strength in one
11 direction and no strength in the other. And the
12 other thing is, and this is related to the fact that
13 it's carbon fiber, and this compares to say a
14 stainless steel plate, this plate cannot be
15 conformed to the shape of the bone. I can't
16 remember the terminology that the surgeons used, but
17 they talk about using the stainless steel plate and
18 essentially pre-deforming the plate to conform to
19 the shape of the bone. That is absolutely
20 impossible with a Carbofixed plate, because if you
21 do that it will crack.

22 Q So there is a lot of information that you
23 gave me. Let's unpack that a bit. With regards to
24 the reduced strength in a perpendicular direction
25 that you contend comes of this type of material

1 because strength is increased in the other
2 direction, what testing have you done to make this
3 determination that strength winds up being reduced
4 in a different direction?

5 MR. FULGINITI: Objection to form.

6 THE WITNESS: The simplest experiment
7 would be a split piece of wood. The wood
8 splits along the grain. It doesn't split
9 perpendicular to the grain for exactly that
10 reason.

11 BY MS. STUPNEVICH:

12 Q So in your opinion the existence of those
13 type of cracks in and of itself indicates that there
14 is a reduced strength in that area?

15 A Oh, yes. Yes.

16 Q Now, did you yourself perform any type of
17 test on this material to kind of gauge that opinion?

18 A No. I only observed the cracks and they
19 exist in the predicted directions.

20 Q And, again, did you consult any literature
21 pertaining to this theory as to the idea that
22 strength is reduced in a perpendicular direction in
23 the PEEK material?

24 A No. Only my general knowledge about such
25 materials.

1 Q Okay. Now let's talk about what you said
2 about the fact that the plate cannot be formed to
3 conform to the shape of the bone. Are you saying
4 that's the case for all carbon fiber plates?

5 A Yes.

6 Q What is your basis for that opinion?

7 A Because such a material cannot plastically
8 deform without breaking the carbon fibers. The
9 carbon fibers will deform very small. And in fact,
10 even if you deform one of these plates until it
11 totally fractures, it will only change its length by
12 2 percent or something like that. Whereas the
13 stainless steel plate will deform by 20 percent.
14 Much more.

15 Q In your opinion, is the carbon fiber
16 composite PEEK material more flexible than stainless
17 steel?

18 MR. FULGINITI: Objection to form.

19 THE WITNESS: It is less deformable and it
20 is as rigid as stainless steel. That is to say
21 it will not plastically deform, but it will
22 elastically deform. So the two will
23 elastically deform by the same amount with
24 roughly the same forces. But the stainless
25 steel, if you bend it with greater force it

1 will then change shape, whereas the carbon
2 fiber plate will break.

3 BY MS. STUPNEVICH:

4 Q What tests have you done in between the
5 two materials to compare that?

6 A I just know that as a material scientist.
7 That's what I do for a living.

8 Q And can you cite any literature that
9 states that?

10 A Oh, my goodness. I'm sorry, I'm not
11 coming up with something. But it's any text on the
12 deformation properties of materials would talk about
13 that.

14 Q Okay. And you also indicate in your
15 report, and this is in line that we were talking
16 about, that the PEEK composite material has low
17 tensile ductility?

18 A Yes. That's the same thing I talked about
19 before, the 2 percent, yes.

20 Q In your opinion is the PEEK carbon fiber
21 composite material plate appropriate for use in
22 chronic nonunions as a general matter?

23 MR. FULGINITI: Objection to form.

24 THE WITNESS: I believe that the plate is
25 appropriate for any application where cracks do

1 not become introduced into the material during
2 installation. So if the plate can be put in
3 position without exceeding the 2 percent
4 deformation then it would be okay. But if it
5 cannot be, then it would not be okay.

6 BY MS. STUPNEVICH:

7 Q Have you reviewed Mr. Curry's medical
8 records, his X-rays, anything like that in this
9 case?

10 A I've certainly read through them. There
11 is a lot of jargon that I don't necessarily
12 understand. But, yes, I've read them.

13 Q Do you believe that in this case the plate
14 could have been put in the position that you're
15 referring to where the cracks would not have
16 formulated?

17 A I believe that it is almost -- it was most
18 likely, almost certain, I would think, that the
19 plate cracked, cracked not broken, but the plate
20 cracked during insertion. And that was probably
21 unavoidable.

22 Q Why do you say that was probably
23 unavoidable?

24 A Because if it were avoidable they would
25 have done it.

1 Q And do you think that it was unavoidable
2 because of the nature of the chronic nonunion that
3 Mr. Curry has?

4 MR. FULGINITI: Objection to form. He
5 wasn't talking about a nonunion.

6 THE WITNESS: Yeah. I was trying to avoid
7 the chronic nonunion, because I'm not sure that
8 I totally understand all of that. But I was
9 referring to the conformity between the plate
10 and the bone.

11 BY MS. STUPNEVICH:

12 Q So let's talk about that. If we are
13 trying to conform a plate to the bone, does the
14 shape of the bone or does the existence of a bone
15 not play a factor in how well or how poorly a plate
16 can conform to it?

17 A The shape of the bone, yes, a great deal.

18 Q Is it fair to say if you have a bone
19 that's extremely damaged, that will affect how well
20 a plate conforms to it?

21 MR. FULGINITI: Objection to form
22 "extremely damaged".

23 THE WITNESS: If the plate is damaged so
24 that it has a shape that does not conform to
25 the plate, then of course that is a problem.

1 BY MS. STUPNEVICH:

2 Q So the bone and its condition is something
3 that affects how well a plate can conform to it,
4 correct?

5 A Oh, yes. Yes. Whereas for a stainless
6 steel plate, that's not the same problem. And as we
7 know, stainless steel plates, plural, replaced this
8 device.

9 Q In your opinion, I'm sorry if I've asked
10 this before, do you believe that the use of this
11 plate was inappropriate in Mr. Curry's specific
12 case?

13 MR. FULGINITI: Objection to form.

14 THE WITNESS: Yes.

15 BY MS. STUPNEVICH:

16 Q Why do you say that?

17 A Because I believe that it was not possible
18 to install the plate without deforming it to the
19 extent that cracks were introduced into the plate.

20 Q And is that based on the condition of his
21 bone that your -- what is your basis for saying that
22 it was not possible to install the plate without
23 deforming it?

24 A Well, because I believe that if it were
25 possible that Dr. Suk and the Carbofix

1 representative would have found a way to do it such
2 that it was not deformed.

3 Q Do you think that the condition of
4 Mr. Curry's bone is something that would have
5 affected whether or not it was possible to install
6 the plate without deforming it?

7 MR. FULGINITI: Objection to form.

8 THE WITNESS: I think that that has
9 everything to do with it.

10 BY MS. STUPNEVICH:

11 Q This type of plate with this type of
12 material we have here, as a general matter, does it
13 need to be bent during surgery?

14 A It needs to be bent a little bit almost
15 always, as long as that bending is less than
16 2 percent strained. And that of course is said --
17 is stated in the literature and is not like a
18 stainless steel plate.

19 Q Which would be bent greater?

20 A You could bend it more.

21 Q Got it. Do you know what type of hardware
22 was utilized by Mr. Curry's surgeon to secure the
23 plate?

24 A Yes. It was titanium six force screws.

25 Q Do you know if these were locking screws?

1 A They appear to be locking screws, just by
2 the fact that they're threaded into the plate.

3 Q Now, with locking screws, the fact that
4 they're screwed into a threaded hole, does that at
5 all eliminate or lessen the need for the plate to be
6 closely aligned with the bone?

7 A No.

8 Q Why not? Wouldn't the locking screws keep
9 it in place once inserted into the thread hole?

10 A The locking screws lock the threads
11 together, but if there is a gap between the plate
12 and the hole and the bone, that gap has to be
13 closed. And that has nothing to do with locking or
14 non-locking screws.

15 Q You also indicate in your report that the
16 main fracture occurred at a location of an abrupt
17 change in curvature of the plate?

18 A Yes.

19 Q Which also coincides with a hole for the
20 longest, most steeply inclined mounting screw. Do
21 you remember that?

22 A Yes.

23 Q What is the significance of this, if any?

24 A At least three different things. One is
25 that the -- if you think of the plate as being

1 somewhat spoon-shaped, then the place where the
2 plate broke is in the most narrow portion of the
3 handle of the spoon where it joins the bowl of the
4 spoon. That's the first thing. The second thing is
5 that the screw is -- at that point position is very
6 highly inclined and, therefore, the locking threads
7 gouge into the plate most severely when it's steeply
8 inclined. And the third reason I can't remember
9 right now.

10 Q Okay. What constitutes an abrupt change
11 in curvature? How would you measure or define that?
12 How does it compare to a slight change in curvature?

13 A Okay. Well, again referring to a spoon,
14 spoon handles are almost never completely straight.
15 They're gently curved and have more or less a
16 constant curvature. But then when you come to the
17 junction between the bowl of the spoon and the
18 handle of the spoon, then the curvature changes very
19 dramatically and it goes in the other direction. So
20 right at that point you have that huge change in
21 curvature.

22 Q So is any extent of curvature potentially
23 problematic with a plate like this?

24 A No. It's not the curvature itself. It's
25 the fact that this indicates the area where the

1 underlying bone undergoes that change of curvature
2 and also where the bone has very high stress.

3 That's the third point I was making, is that that
4 change in the curvature is where the stresses are
5 highest.

6 Q Okay. You said you reviewed some of
7 Mr. Curry's medical records. Do you recall
8 reviewing any images or any records that reference a
9 black drainage that had come from the incision?

10 A A what?

11 Q Black drainage.

12 A Oh, yes. Yes.

13 Q In your opinion was this entirely the
14 result of the plate failing?

15 A Certainly the black fibrous material
16 contained within the drainage had to be from the
17 fractured device.

18 Q Is there a possibility that maybe an
19 infection contributed to this result or did it all
20 look as though it had come from the plate?

21 MR. FULGINITI: Objection to form.

22 THE WITNESS: I don't pretend to be --

23 BY MS. STUPNEVICH:

24 Q Not from a medical standpoint. I mean
25 based on your review and your knowledge of

1 materials.

2 MR. FULGINITI: Materials or inspections?

3 MS. STUPNEVICH: Materials.

4 MR. FULGINITI: He's answered that, but go
5 ahead.

6 THE WITNESS: The pathology report
7 referred to fibrous material that was removed
8 from the wound area, and that's certainly from
9 the plate.

10 BY MS. STUPNEVICH:

11 Q If the plate in this case was in fact
12 fractured during the implantation, would you expect
13 to see a widespread failure amongst a significant
14 number of implants of this kind?

15 MR. FULGINITI: Objection to form.

16 THE WITNESS: I think the question is if
17 this plate were cracked during installation and
18 that led to the eventual failure would I expect
19 that other plates would have been cracked
20 during installation, therefore, would fail.

21 BY MS. STUPNEVICH:

22 Q Right.

23 A I don't know how many other similar
24 installations there are, but I think that logic
25 would tell you that both should be examined

1 carefully.

2 Q But looking at this type of a fracture and
3 the tests you performed on the plate, the
4 inspections that you've done, would you anticipate
5 that with a plate of this nature you would see a lot
6 of fracture incidents?

7 MR. FULGINITI: Objection to form.

8 THE WITNESS: If plates are installed in
9 situations where you exceed the 2 percent
10 ductility and induce cracks, that is very
11 dangerous and very likely will form premature
12 failures. I might add here that in engineering
13 in general we assume that all structural
14 devices contain cracks. And the question then
15 is how big is the biggest possible crack and
16 lets me know how big the biggest possible crack
17 is, then we can calculate what is the highest,
18 the biggest stress that we can apply to that.
19 And that's the basis of the entire field of
20 fracture mechanics.

21 BY MS. STUPNEVICH:

22 Q Makes sense. Dr. Pope, also you indicate
23 in your report that there is no evidence of total
24 fracture of the plate during installation, but
25 partial cracking cannot be ruled out; is that

1 correct?

2 MR. FULGINITI: Where are you reading
3 from?

4 MS. STUPNEVICH: I'm reading from Page 3.

5 BY MS. STUPNEVICH:

6 Q The paragraph that starts with, "This
7 raises the question of whether," and if you go down
8 to line 3, "near the fracture corresponds to the
9 suture hole on the right side of the plate. There
10 is no evidence of total fracture of the plate during
11 installation, but partial cracking cannot be ruled
12 out."

13 A That's correct.

14 Q Isn't it true that you also cannot
15 conclusively rule out the possibility that partial
16 cracking did not occur at the implant? So in other
17 words, we can not say with certainty that this is
18 when it happened?

19 MR. FULGINITI: Objection to form.

20 THE WITNESS: I can say with certainty
21 that the cracks that were seen in the cross
22 sectional views towards the end of my report on
23 37, 36 et cetera, those were definitely formed
24 during installation. And other cracks close to
25 the fracture surface, for example, the screw

1 that went into hole number 5 certainly produced
2 cracks in that hole as well. So it is quite
3 clear that there were preexisting cracks from
4 the moment that this plate was installed.

5 BY MS. STUPNEVICH:

6 Q And this is -- I don't want to have you
7 repeat what you told me during the course of your
8 deposition, but this is based on your overview of
9 the cracks and what they visually look like to you
10 and your knowledge of the materials?

11 A Yes.

12 Q Can you conclusively rule out that those
13 cracks that you reference specifically in 36 and 37
14 weren't caused by something like secondary trauma or
15 just biological complications or something else?

16 MR. FULGINITI: Objection to form.

17 THE WITNESS: No. I see no other way that
18 those cracks could have been formed except
19 during the insertion of the screws.

20 BY MS. STUPNEVICH:

21 Q Okay. I think that might be all I have
22 for you. Give me one second. I'll look through my
23 notes.

24 MR. FULGINITI: Can we step out for a
25 second?

1 MS. STUPNEVICH: Sure.

2 * * *

3 (Whereupon, a brief recess was taken.)

4 * * *

5 MS. STUPNEVICH: That's all I have for
6 you.

7 MR. FULGINITI: I have a couple questions.

8 E X A M I N A T I O N

9 BY MR. FULGINITI:

10 Q For the record, Ken Fulginiti. I
11 represent Mr. Curry. I just want to be clear. With
12 regard to the use of this plate with Mr. Curry, I
13 want to make sure I understand. You're not saying
14 that there was anything outwardly that would suggest
15 to Dr. Suk that this was the wrong application,
16 correct?

17 MR. FULGINITI: Objection to form.

18 THE WITNESS: Yeah. I think it's quite
19 obvious that, of course, Dr. Suk thought it was
20 the correct application, but also the company
21 representative there didn't say anything that
22 it was the wrong application. So I believe
23 that, yes indeed, there was appeared outwardly
24 to be the correct application of this plate.

1 BY MR. FULGINITI:

2 Q And I think what you were saying before is
3 that the potential for complications here is
4 whenever you have this greater than 2 percent number
5 that you were talking about?

6 A Yes.

7 Q Okay. You're not in any way saying or
8 suggesting that Dr. Suk misused the product or
9 anything like that?

10 A No, I believe not. And again, it's
11 because everything seemed to have gone smoothly, as
12 they noted, and also the company representative was
13 there and made no comments about misuse or anything
14 like that.

15 Q And this 2 percent that you were talking
16 about, I didn't see that anywhere in the
17 instructions for use. Did you see that?

18 A No, it is not in there. It's only in the
19 test results that are contained in the FDA
20 information.

21 MR. FULGINITI: Okay. I have no further
22 questions.

23 E X A M I N A T I O N

24 BY MS. STUPNEVICH:

25 Q Just one or two follow-up. When you say

1 that everything appeared outwardly to be correct for
2 the application, what do you mean by that? Sorry.

3 Let me clarify. During the procedure on Mr. Curry.

4 A Well, I conclude that based on the fact
5 that first of all Dr. Suk said that things went
6 smoothly and normally or something like that. But
7 also there is no evidence that the Carbofix
8 representative pointed out any difficulty or problem
9 or made any statement that this should be done
10 differently or whatever. So it appears as though
11 both of those people thought it was okay.

12 Q But you're saying it's based solely on the
13 operative report, I assume? You obviously weren't
14 present during the procedure.

15 A No. Just --

16 MR. FULGINITI: Objection to form.

17 THE WITNESS: Just the information that we
18 have available, yes.

19 BY MS. STUPNEVICH:

20 Q Okay. But as far as appearing outwardly
21 to be the correct application, are you contending
22 that Mr. Curry outwardly appeared to be an
23 appropriate candidate for this plate?

24 A I believe that Mr. Curry's humerus
25 appeared to be an appropriate place to use this

1 plate to Dr. Suk and to Mr. -- I forget his name
2 already, but the company representative.

3 MS. STUPNEVICH: Okay. That's all I have
4 for you.

5 MR. FULGINITI: A full-size transcript is
6 fine.

7 MS. STUPNEVICH: I'd like an E-mailed
8 transcript.

9 * * *

10 (Witness excused.)

11 * * *

12 (Whereupon, the deposition concluded
13 at 12:55 p.m.)

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2 I N D E X
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